IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Masini

Serial No.: 10/685,620 Group No.: 3738

Filed: Oct. 15, 2003 Examiner: Bruce Snow

For: BONE-CONSERVING ORTHOPEDIC INSTRUMENTATION AND APPLIANCES

APPELLANT'S APPEAL BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party and interest in this case is MedIdea, LLC, by assignment.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 23 claims. Claims 1-23 are pending, rejected and under appeal. Claims 1, 9 and 17 are the independent claims.

IV. Status of Amendments Filed Subsequent Final Rejection

No after-final amendments have been filed.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to a bone-conserving orthopedic apparatus, comprising a cutting guide for performing a set of lateral and medial resections, the cutting guide including: first and second saw-receiving slots, each slot being associated with a respective one of the lateral and medial resections, and wherein the resections resulting from the use of the slots slope inwardly along different planes from a respective outer medial and lateral surface. (Specification, page 8, line 14 to page 9, line 4; Figures 6A and 6B).

Independent claim 9 is directed to a bone-conserving orthopedic apparatus, comprising a cutting guide for a resecting a pair of lateral and medial protrusions, each protrusion having a sidewall sloping toward a central valley region, the cutting guide including: first and second saw-receiving slots the first slot being substantially conformal to the sidewall of one of the protrusions, and the other slot being substantially conformal to the sidewall of the other protrusion, and wherein the resections resulting from the use of the slots do not lie in the same plane. (Specification, page 8, line 14 to page 9, line 4; Figures 6A and 6B).

Independent claim 17 is directed to an orthopedic apparatus for use with a bone having a longitudinal axis, the apparatus comprising a cutting guide including a stem insertable into the bone in substantial alignment with the longitudinal axis; and at least one saw-receiving slot on the cutting guide for resecting the bone along a plane which is not transverse to the longitudinal axis. (Specification, page 8, line 14 to page 9, line 4; Figures 6A and 6B).

VI. Grounds of Objection/Rejection To Be Reviewed On Appeal

A. The rejection of claims 1-6 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,980,526 to Johnson et al., and separately under 35 U.S.C. §102(b) over U.S. Patent No. 5,879,393 to Whiteside et al.

B. The rejection of claims 7, 8, 15, 16, 22 and 23, wherein claims 7, 15, 22 and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,980,526 to Johnson et al. and claims 7, 8, 15, 16, 22 and 23 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,879,393 to Whiteside et al.

C. The rejection of claims 9-14 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent

No. 5,980,526 to Johnson et al., and separately under 35 U.S.C. §102(b) over U.S. Patent No. 5,879,393 to Whiteside et al.

D. The rejection of claims 17-23 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,980,526 to Johnson et al. and separately under 35 U.S.C. §102(b) over U.S. Patent No. 5,879,393 to Whiteside et al.

VII. Argument

A. Claims 1-6, wherein claims 2-6 stand/fall with claim 1

Claim 1 includes the limitation of a cutting guide **including first and second saw-receiving slots** configured such that "the resections resulting from the use of **the slots** slope inwardly along different planes from a respective outer medial and lateral surface." (Emphasis added). From this language, it is clear that the same guide includes both slots, and that the use of both results in resections that "slope inwardly."

Claim 1 stands rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,980,526 to Johnson et al. on the grounds that the apparatus of Johnson has "first and second saw-receiving slots 100, 110" which are "fully capable of wherein [sic] ... the resections resulting from the use of the slots slope inwardly along different planes from a respective outer medial and lateral surface." (Final Office Action, bottom of page 4 to top of page 5.) This is all the Examiner has to say. No evidence is presented as to how the apparatus of Johnson is "fully capable" of performing such resections.

The apparatus of Johnson is shown below along with the intended installation (Figure 7). The "slots" relied upon by the Examiner are shown at 100 and 110. Appellant cannot figure out how the use of slots 100, 110 result in resections "that slope inwardly along different planes from a respective outer medial and lateral surface." (The Examiner's own words.) Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992). At the very least, the Examiner should articulate where, in the prior art, one would find the suggestion or motivation in support of the conclusion that the reference is "fully capable of" a particular function of interest.

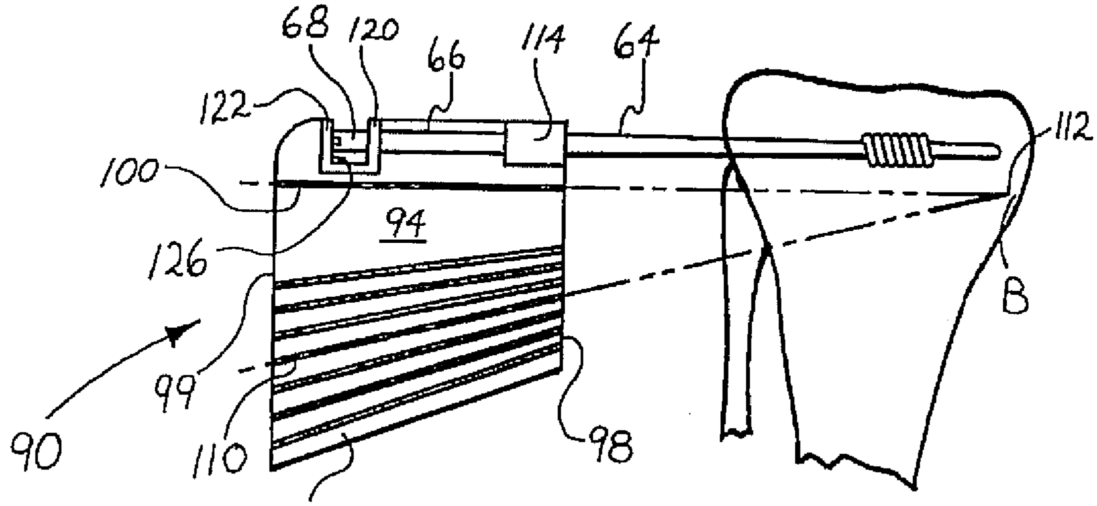


Fig. 7

Perhaps the Examiner is relying on a theory of 'inherency.' However, that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." Id. at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

Claim 1 also stands rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,879,393 to Whiteside et al. The Examiner's argument is that "[r]egarding claim 1, see figure 1, wherein first and second slots for example elements 35A and 35B which wherein [sic] the apparatus can be tilted *while cutting* to form resections that slope inwardly." (Emphasis added) Figures 1, 4 and 7 of Whiteside are reproduced below:

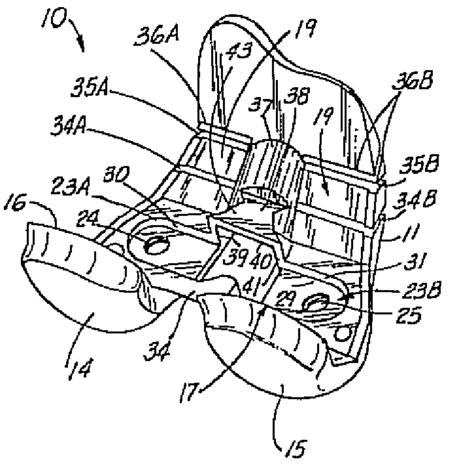


FIG. 1

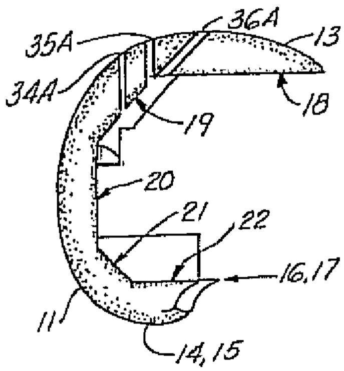


FIG. 4

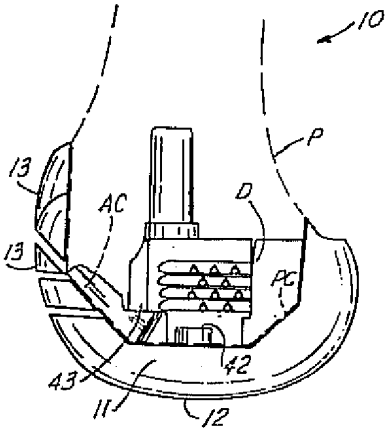


FIG. 7

Whiteside reads as follows beginning at col. 3, line 21: "Trial body 11 can provide a plurality of five flat surfaces 18, 19, 20, 21, 22 that are used to form a load transfer interface with a patient's surgically prepared femur F. The femur F is surgically prepared as shown in FIG. 7 to provide five cut surfaces. These surgically cut surfaces on femur F correspond in shape and placement to the surfaces 18, 19, 20, 21, and 22 of trial body 11.

"When the femur F is surgically cut (see FIG. 7), the surgeon forms a plurality of five cut surfaces including: a distal D cut surface, anterior A and posterior P cut surfaces, and anterior and posterior chamfer cut surfaces AC, PC. When a surgeon performs a revision surgical case, these cut surfaces are already present on the femur from a previous surgery. When the surgeon removes the previous implant in a revision case, the femur F resembles the shape shown in phantom lines in FIG. 7. The surgeon then uses the trial apparatus 10 to reshape the distal femur F and to determine the correct size for a final prosthesis to be used in the revision surgery, replacing the old removed implant. The five surgically prepared surfaces are reshaped somewhat using trial body 11. The cutting surfaces 16, 17 shave bone from the posterior condylar cut surface P of the femur F. Cutting edges 68A & 69A and rasping surface 71 on the module 50 also cut and shave bone."

Again, the Examiner's argument here is that "the apparatus can be tilted *while cutting* to form resections that slope inwardly." Appellant cannot figure out how the apparatus of Whiteside can be tilted while cutting. As best seen in Figure 7, several surfaces are prepared on the distal end of the femur to make intimate contact with surfaces 18, 19, 21, 22 of the apparatus best seen in Figure 4. The whole point of this arrangement is to hold the apparatus perfectly still while further resections are performed. It is Appellant's position that unless the Examiner can explain how the apparatus can be tilted while cutting to form resections that slope inwardly, *prima facie* anticipation has not been established.

B. Claims 7, 8, 15, 16, 22 and 23.

Claims 7, 15, 22 and 23 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,980,526 to Johnson et al. The Examiner's "argument" is that "the prosthetic element is interpreted as the wedge-shaped bone [sic] with [sic] is removed and has "a set of bone-contacting surfaces." This rejection is incomprehensible. To which "prosthetic element" is the Examiner referring? Is the Examiner stating that the "prosthetic element" is made of bone? What has "a set of bone-contacting surfaces"?

Claims 7, 8, 15, 16, 22 and 23 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,879,393 to Whiteside et al. The argument presented by the Examiner are as follows:

"Regarding the prosthesis, see at least 3:38." Column 3, line 38 of Whiteside reads as follows: "the correct size for a final prosthesis to be used in the"

"Regarding wedge-shaped augments, see elements 77."

Appellant cannot determine how such statements *meet all of the limitations* of the respective claims.

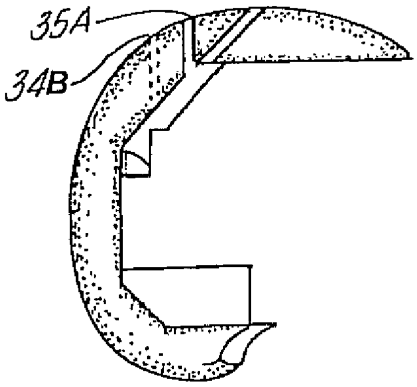
C. Claims 9-14, wherein claims 10-14 stand/fall with claim 9.

Claim 9 stands rejected under 35 U.S.C. §102(b) over Johnson on the grounds that "the apparatus is fully capable of performing the method of claims 2-6 and 9-14. However, all of these claims are apparatus claims. Claim 9 is an independent apparatus claim that reads as follows:

> 9. Bone-conserving orthopedic apparatus, comprising:
>
> a cutting guide for a resecting a pair of lateral and medial protrusions, each protrusion having a sidewall sloping toward a central valley region, the cutting guide including:
>
> first and second saw-receiving slots the first slot being substantially conformal to the sidewall of one of the protrusions, and the other slot being substantially conformal to the sidewall of the other protrusion, and wherein the resections resulting from the use of the slots do not lie in the same plane.

How can Johnson et al. read on "this method"?

Claim 9 also stands rejected under 35 U.S.C. §102(b) over Whiteside. The Examiner's rejection reads as follows: "Regarding claim 9, see first and second slots 35A and 34B, for example."
To follow the Examiner's logic, Appellant has taken the liberty of redrawing Figure 4 of Whiteside to show slots 35A and 34B:



As can be seen, these slots are on either side of the apparatus, and are parallel to one another. Appellant's claim 9 sets forth a cutting guide for a resecting a pair of lateral and medial protrusions, each protrusion having a sidewall *sloping toward a central valley region.* The cutting guide includes first and second saw-receiving slots, wherein the first slot is conformal to the sidewall of one of the protrusions, and the other slot is conformal to the sidewall of the other protrusion. Thus the slots, as well as the protrusions, *slope toward a central valley region.* This is neither taught nor suggested by the prior art, and the recitation is more than just a method. *Prima facie* anticipation has not been established.

D. Claims 17-23, wherein claims 18-20 stand/fall with claim 17.

Although claim 17 stands rejected under 35 U.S.C. §102(b) over Johnson and separately under 35 U.S.C. §102(b) over Whiteside, the Examiner does not cite any substantive comparisons. Rather, from what Appellant can gather, claim 17 stands rejected on the grounds that "Applicant is simply unreasonable." However, this is not a statutory basis for rejection. Title 35, section 102 begins (with emphasis added): "A person *shall be entitled* to a patent unless..." Following this are seven loss-of-right provisions, (a)-(g), none of which imply that "a person shall be entitled to a patent unless that person is unreasonable." There is nothing "unreasonable" about seeking protection to which an applicant is entitled. A claim cannot be "unreasonable."

Even if an Examiner thinks a claim is "unreasonable," that is not an excuse for avoiding the examination process. "An Examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis for the rejection." See In re Warner, 379 F.2d 1011,1017,154 USPQ 173, 177 (CCPA 1967), *cert. denied*, 389U.S. 1057 (1968). Although this case is directed to obviousness, clearly the same principle applies – or should apply – to anticipation.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

Date: Jan. 2, 2007

By: ______________________________
John G. Posa
Reg. No. 37,424
Gifford, Krass, Groh, Sprinkle,
Anderson & Citkowski, P.C.
PO Box 7021
Troy, MI 48007-7021
(734) 913-9300

APPENDIX A

CLAIMS ON APPEAL

1. Bone-conserving orthopedic apparatus, comprising:

a cutting guide for performing a set of lateral and medial resections, the cutting guide including:

first and second saw-receiving slots, each slot being associated with a respective one of the lateral and medial resections, and wherein the resections resulting from the use of the slots slope inwardly along different planes from a respective outer medial and lateral surface.

2. The orthopedic apparatus of claim 1, wherein the lateral and medial resections are performed with respect to a pair of distal femoral condyles.

3. The orthopedic apparatus of claim 2, wherein the planes corresponding to the two resections intersect proximate to an intercondylar region.

4. The orthopedic apparatus of claim 2, wherein the two resections are performed as part of a distal resection of a human femur.

5. The orthopedic apparatus of claim 2, wherein the two resections are performed as part of a posterior resection of a human femur.

6. The orthopedic apparatus of claim 2, wherein the two resections are performed as part of an anterior resection of a human femur.

7. The orthopedic apparatus of claim 1, further including a prosthetic element having a set of bone-contacting surfaces corresponding to the resections.

8. The orthopedic apparatus of claim 1, adapted for use with an existing prosthetic element having co-planar lateral and medial bone-contacting surfaces, the apparatus further comprising:

a pair of wedge-shaped augment elements, each shaped to consume the space between one of the resections and one of the bone-contacting surfaces.

9. Bone-conserving orthopedic apparatus, comprising:

a cutting guide for a resecting a pair of lateral and medial protrusions, each protrusion having a sidewall sloping toward a central valley region, the cutting guide including:

first and second saw-receiving slots the first slot being substantially conformal to the sidewall of one of the protrusions, and the other slot being substantially conformal to the sidewall of the other protrusion, and wherein the resections resulting from the use of the slots do not lie in the same plane.

10. The orthopedic apparatus of claim 9, wherein the protrusions are condyles.

11. The orthopedic apparatus of claim 9, wherein the resections intersect proximate to an intercondylar region.

12. The orthopedic apparatus of claim 9, wherein the two resections are performed as part of a distal resection of a human femur.

13. The orthopedic apparatus of claim 9, wherein the two resections are performed as part of a posterior resection of a human distal femur.

14. The orthopedic apparatus of claim 9, wherein the two resections are performed as part of an anterior resection of a human distal femur.

15. The orthopedic apparatus of claim 9, further including a prosthetic element having a set of bone-contacting surfaces corresponding to the resections.

16. The orthopedic apparatus of claim 9, adapted for use with an existing prosthetic element

having co-planar lateral and medial bone-contacting surfaces, the apparatus further comprising:

a pair of wedge-shaped augment elements, each shaped to consume the space between one of the resections and one of the bone-contacting surfaces.

17. Orthopedic apparatus for use with a bone having a longitudinal axis, the apparatus comprising:

a cutting guide including a stem insertable into the bone in substantial alignment with the longitudinal axis; and

at least one saw-receiving slot on the cutting guide for resecting the bone along a plane which is not transverse to the longitudinal axis.

18. The orthopedic apparatus of claim 17, wherein the bone is a human femur, and the stem is inserted into an intramedullary canal.

19. The orthopedic apparatus of claim 18, wherein the slot is used to perform a distal resection of the bone.

20. The orthopedic apparatus of claim 18, wherein the slot is used to perform an anterior resection of the bone.

21. The orthopedic apparatus of claim 18, wherein the slot is used to perform a posterior resection of the bone.

22. The orthopedic apparatus of claim 18, further including a prosthetic element having a bone-contacting surface corresponding to the resection.

23. The orthopedic apparatus of claim 18, adapted for use with an existing prosthetic element having a bone-contacting surface which is substantially transverse to the longitudinal axis, the apparatus further comprising:

a wedge-shaped augment element to consume the space between the resection and the bone-contacting surface.

APPENDIX B

EVIDENCE

None.

APPENDIX C

RELATED PROCEEDINGS

None.